DEPARTMENT OF ENERGY
Federal Energy Regulatory Commission
18 CFR Part 154
[Docket No. RM12–14–000; Order No. 776]

Annual Charge Filing Procedures for Natural Gas Pipelines


ACTION: Final rule.

SUMMARY: In this Final Rule, the Federal Energy Regulatory Commission (Commission or FERC) is amending its regulations to revise the filing requirements for natural gas pipelines that choose to recover Commission-assessed annual charges through an annual charge adjustment (ACA) clause. Currently, natural gas pipelines utilizing an ACA clause must make an annual tariff filing to reflect a revised ACA unit charge authorized by the Commission for that fiscal year. To reduce the regulatory burden on these pipelines, the Commission will eliminate this annual filing requirement. In its place, the Commission will require natural gas pipelines utilizing an ACA clause to incorporate the Commission-authorized annual charge unit rate by reference to that rate, as published on the Commission’s Web site located at http://www.ferc.gov.

I. Background

A. Commission Regulations

2. The Commission is required to “assess and collect fees and annual charges in any fiscal year in amounts equal to all of the costs incurred by the Commission in that fiscal year.” To accomplish this, the Commission created the annual charges program, which is designed to recover the costs of administering the natural gas, oil, and electric programs by calculating the costs of each program, net of filing fees, and properly allocating them among the three programs. This proceeding applies only to the recovery of annual charges assessed to entities in the natural gas program.

3. The provisions governing the assessment of annual charges are codified in Part 382 of the Commission’s regulations. In brief, the Commission calculates the costs of administering the natural gas regulatory program, it assesses those costs to natural gas pipeline companies (Pipelines), and properly allocates them among Pipelines.

III. Petitions


3. The provisions governing the annual charges program as the Commission’s regulation of the natural gas industry under the Natural Gas Act; National Gas Policy Act of 1978; Alaska Natural Gas Transportation Act; Public Utility Regulatory Policies Act; Department of Energy Organization Act; Outer Continental Shelf Lands Act; Energy Security Act; Regulatory Flexibility Act; Crude Oil Windfall Profits Tax Act; National Environmental Policy Act; National Historic Preservation Act.

4. For the purposes of this proceeding, we use the term natural gas pipeline company (Pipelines) as it is defined in 18 CFR 382.102(d) (2012). See Omnibus Budget Reconciliation Act, Public Law 99–509, Title III, Subtitle E, Sec. 3401, 1986 U.S. Code Cong. & Ad. News (100 Stat.) 1874, 1890–91 (codified at 42 U.S.C. 7178 (2012)).


7. Id. at 382.102(d) (defining the “natural gas regulatory program” as the Commission’s regulation of the natural gas industry under the Natural Gas Act; National Gas Policy Act of 1978; Alaska Natural Gas Transportation Act; Public Utility Regulatory Policies Act; Department of Energy Organization Act; Outer Continental Shelf Lands Act; Energy Security Act; Regulatory Flexibility Act; Crude Oil Windfall Profits Tax Act; National Environmental Policy Act; National Historic Preservation Act).

8. For the purposes of this proceeding, we use the term natural gas pipeline company (Pipelines) as it is defined in 18 CFR 382.102(a) (2012). (“any person: (1) Engaged in natural gas sales for resale or natural gas transportation subject to the jurisdiction of the Commission under the Natural Gas Act whose sales for resale and transportation exceed 200,000 MCF at 14.73 psi (60 °F) in any of the three calendar years immediately preceding the fiscal year for which the Commission is assessing annual charges; and (2) Not engaged solely in “first sales” of natural gas as that term is defined in section 2(21) of the Natural Gas Policy Act of 1978; and (3) To whom the Commission has not issued a Natural Gas Act Section 7(f) declaration; and (4) Not holding a limited jurisdiction certificate.”

9. Id.

10. Id.

must apply the ACA unit charge to the usage component of rate schedules with two-part rates. A company may recover annual charges through an ACA unit charge only if its rates do not otherwise reflect the costs of annual charges assessed by the Commission under § 382.106(a) of this chapter. The applicable annual charge, required by § 382.103 of this chapter, must be paid before the company applies the ACA unit charge.\(^{12}\)

6. Pipelines that seek to recover annual charges through an ACA clause must file a tariff record containing a statement that the company is collecting an ACA per unit charge, as approved by the Commission, applicable to all the pipeline’s sales and transportation rate schedules, the per unit charge of the ACA, the proposed effective date of the tariff change (30 days after the filing of the tariff sheet or section, unless a shorter period is specifically requested in a waiver petition and approved), and a statement that the pipeline will not recover any annual charges recorded in FERC Account 928 in a proceeding under subpart D of [part 154 of the Commission’s regulations].\(^{13}\)

Additionally, the Commission requires these Pipelines to file revised tariff records to reflect changes to the ACA unit charge authorized by the Commission each fiscal year.\(^{14}\)

7. Each year the Commission sets the ACA unit charge for the natural gas program in July.\(^{15}\) Pipelines that wish to begin collecting the ACA unit charge on the first day of the fiscal year are required to file revised tariff records reflecting changes in the ACA unit charge by September 1 of each year, to be effective October 1 of that year.\(^{16}\) So long as the Pipeline has paid its annual charge to the Commission, the Commission will accept the tariff records, and they will go into effect on October 1. To the extent that the ACA unit charge remains the same from one year to the next, existing Pipelines that already reflect that ACA unit charge in their tariffs need not make a filing for that year. This annual process is designed to ensure that Pipelines collect charges for the entire fiscal year, as defined in Part 382 of the Commission’s regulations.

8. In 2011, the Commission received 145 filings to reflect the annual change in the ACA unit charge. In years in which the ACA unit charge does not change, there are fewer filings. However, some Pipelines, such as those that have recently gone into service and have been billed an annual charge, are still permitted to submit a filing to the Commission in order to pass along the annual charge to their customers.

**B. Notice of Proposed Rulemaking (NOPR)**

9. On October 18, 2012, the Commission issued a NOPR proposing to eliminate the ACA unit charge filing requirement set forth in Part 154 of the Commission’s regulations. The Commission received comments in support of the NOPR from the American Gas Association, Spectra Entitas, Interstate Natural Gas Association of America (INGAA) and KO Transmission Company. In addition to INGAA’s comments in support of the NOPR, INGAA proposes a minor modification to the NOPR to eliminate unnecessary confusion and to reduce the filing burden on pipelines. Specifically, INGAA proposes requiring pipelines to submit compliance filings 30 or 60 days prior to the proposed October 1, 2013, effective date of this Final Rule.\(^{17}\)

**II. Discussion**

10. In an effort to reduce the regulatory burden associated with annual tariff filings to reflect the current year’s ACA unit charge, the Commission will eliminate the annual filing requirement for Pipelines utilizing an ACA clause. In its place, the Commission will require Pipelines utilizing an ACA clause to incorporate the Commission-authorized ACA unit rate by reference to that rate, as published on the Commission’s Web site. Accordingly, Pipelines that wish to continue utilizing an ACA clause will be required to make a one-time tariff revision that incorporates the ACA unit charge published on the Commission’s Web site into the Pipeline’s tariff as the ACA unit charge for the relevant fiscal year.\(^{18}\)

11. The Commission is aware that in addition to the basic statutory requirement that all rates and charges be on file with the Commission,\(^{19}\) the filing requirements associated with the annual revisions to the ACA unit charge serve important practical functions. First, the annual tariff filing (and the Commission’s acceptance of that filing) establishes an effective date upon which the Pipeline is entitled to begin collecting that fiscal year’s ACA unit charge. Second, the annual filing provides the Commission with an opportunity to ensure that the Pipeline has actually paid the annual charge that it seeks to recover from customers.\(^{20}\)

12. Because the annual filing requirement will be eliminated under the reforms set forth in this Final Rule, the Commission will require Pipelines utilizing an ACA clause to incorporate by reference into their tariffs the ACA unit charge specified in the annual notice issued by the Commission entitled “FY [Year] Gas Annual Charges Correction for Annual Charges Unit Charge.” This ACA unit charge shall be effective on the first day of October following issuance of this notice and shall extend to the last day of September the following year (i.e., the duration of the fiscal year). However, the ACA unit charge shall only be incorporated by reference into the Pipeline’s tariff, and thereby assessed to shippers, if the Pipeline has paid its annual assessment, as reflected on a new notice, entitled “Payment Status of Pipeline Billings—FY [Year],” that the Commission will issue each year. This notice will identify the Pipelines that have been assessed annual charges for a fiscal year and indicate whether they have paid their charges and are, therefore, authorized to recover the ACA unit charge from shippers. The Commission will issue the “Payment Status of Pipeline Billings—FY [Year]” notice on the last business day of the fiscal year, and provide updates as necessary. All of the documents can be found on the Annual Charges page of the Natural Gas section of the Commission’s Web site, located at [http://www.ferc.gov](http://www.ferc.gov).

13. We emphasize that the only thing changed by this Final Rule is the filing requirement for those Pipelines that utilize an ACA clause. This Final Rule does not prevent Pipelines from continuing to recover annual charges assessed by the Commission through their transportation rates, as established in a general rate case. Nor does this Final Rule modify how the Commission calculates the costs of the natural gas.

\(^{12}\) Id. at 154.402(a).

\(^{13}\) Id. at 154.402(b).

\(^{14}\) Id. at 154.402(c).

\(^{15}\) The Commission publishes this change via a notice entitled, “FY [Year] Gas Annual Charges Correction for Annual Charges Unit Charge,” which is available on the Commission’s Web site, located at [http://www.ferc.gov](http://www.ferc.gov).

\(^{16}\) See 18 CFR 382.102(i) (2012) (defining “fiscal year” as the twelve-month period that begins on the first day of October and ends on the last day of September); see also id. at 154.402(b)(3) (requiring the proposed effective date of the tariff change revising the ACA unit charge to be 30 days after the date the change is filed, unless a shorter period is specifically requested in a waiver petition and approved).

\(^{17}\) See INGAA Comments at 2–3.

\(^{18}\) See 18 CFR 382.102(i) (2012) (defining “fiscal year” as the twelve-month period that begins on the first day of October and ends on the last day of September).


\(^{20}\) Order No. 472, FERC Stats. & Regs. ¶ 30,746 at 30,629–30 (explaining that Pipelines may only collect those annual charges that they have already paid to the Commission).
regulatory program or how the ACA unit charge is calculated or assessed.

14. We are taking this action as part of our commitment to continually review our regulations and eliminate those requirements that impose an unnecessary burden on regulated entities. We find that requiring Pipelines to incorporate the ACA unit charge by reference to the notices published on the Commission’s Web site will retain all of the transparency and consumer safeguards embodied in the Commission’s existing regulations. However, it will eliminate approximately 145 filings each year, thereby reducing the regulatory burden on the Pipelines and the Commission.

III. Compliance

15. This Final Rule requires Pipelines to implement the changes set forth herein in time for the 2014 fiscal year. Accordingly, the Commission will require each Pipeline utilizing an ACA clause to make a one-time compliance filing revising its tariff to incorporate by reference the ACA unit charge published on the Commission’s Web site, as discussed above. In order to give Pipelines subject to these modifications adequate time to implement these changes, this compliance filing will be due 60 days before the required effective date of October 1, 2013.

IV. Information Collection Statement

16. The Office of Management and Budget’s (OMB) regulations require approval of certain information collection requirements imposed by agency rules.21 Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of a rule will not be penalized for failing to respond to this collection of information unless the collection of information displays a valid OMB control number.

17. The Commission sought comments on its burden estimates associated with adoption of the NOPR proposals. In response to the NOPR, no comments were filed addressing the reporting burden estimates imposed by these requirements. Therefore the Commission will use the same estimates in this Final Rule.

18. The following FERC–542 reporting requirements contained in this Final Rule are being submitted to the Office of Management and Budget (OMB) for review under section 507(d) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(d). The burden estimates reflect the time necessary for respondents to update their tariffs according to this Final Rule. Additionally, these estimates highlight reductions to the burden since respondents will no longer have to file ACA charge tariff adjustments. More specifically, the Commission estimates it will require eight hours per response to make the “one-time” (during the first year only) compliance tariff changes set forth in this Final Rule to place the new tariff language into effect. However, in each year (including the 1st year), the Commission also estimates that filers will see a two-hour reduction in burden per response from no longer filing ACA charge tariff adjustments. The following table displays the estimated annual burden hour impact of the Final Rule.

<table>
<thead>
<tr>
<th>FERC–542 in the final rule in RM12–14</th>
<th>Number of respondents</th>
<th>Number of responses per respondent per year</th>
<th>Total number of responses per year</th>
<th>Addition of average burden hours per response</th>
<th>Reduction of average burden hours per response</th>
<th>Net average burden per response</th>
<th>Estimated total annual burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1 ...................................</td>
<td>145</td>
<td>1 Compliance Filing.</td>
<td>145</td>
<td>+8 (Compliance Filing).</td>
<td>0</td>
<td>+8</td>
<td>+1160</td>
</tr>
<tr>
<td>Year 1 ...................................</td>
<td>145</td>
<td>1 Avoided ACA filing.</td>
<td>145</td>
<td>0</td>
<td>−2 (ACA filing)</td>
<td>−2</td>
<td>−290</td>
</tr>
<tr>
<td>Year 1 SUB-TOTAL.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>+6</td>
<td>+870</td>
</tr>
<tr>
<td>Year 2 ...................................</td>
<td>145</td>
<td>1 Avoided ACA filing.</td>
<td>145</td>
<td>0 −2 (ACA filing)</td>
<td>−2</td>
<td>−2</td>
<td>−290</td>
</tr>
<tr>
<td>Year 3 ...................................</td>
<td>145</td>
<td>1 Avoided ACA filing.</td>
<td>145</td>
<td>0 −2 (ACA filing)</td>
<td>−2</td>
<td>−2</td>
<td>−290</td>
</tr>
<tr>
<td>NET TOTAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>+290</td>
<td></td>
</tr>
</tbody>
</table>

To understand the burden estimates above, reference the following equation:

Year 1 + Year 2 + Year 3 → +870 hours − 290 hours − 290 hours = +290 hours.

The net total additional annual burden associated with this Final Rule over Years 1–3 period is 290 hours. Thus, the average additional annual burden for Years 1–3 is 97 hours (290 hours ÷ 3 years = 97 hours per year). Further, the Commission estimates that each respondent (on average) should experience a decrease to the annual burden (of 2 hours per year) due to the avoidance of the ACA filing.

Information Collection Costs: The Commission seeks comments on the costs to comply with these requirements. It has projected the average cost for all respondents to be the following:22

- One-time total cost in Year 1 of $51,330 (870 hours * $59/hour)
- Avoided cost per year (starting in Year 1) of $17,110 (290 hours * $59/hour)

22. The cost figures are derived by multiplying the total hours to prepare a response [hours] by an hourly wage estimate of $59 (a composite estimate that includes legal, technical and support staff wages and benefits obtained from the Bureau of Labor Statistic data at http://bls.gov/oes/current/naics3_221080.htm and http://www.bls.gov/news.release/ecoco.tn0.htm).
gas pipelines, starting with the fifth year and in each year thereafter.

Internal Review: The Commission has reviewed the requirements pertaining to the modification of the Commission’s regulations and made a preliminary determination that the revisions are necessary to reduce the burden imposed by the Commission on the natural gas industry. The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

19. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: DataClearance@ferc.gov, phone: (202) 502–8663, fax: (202) 273–0873].

20. Comments concerning the collection of information and the associated burden estimate, should be sent to the Commission in this docket and to the Office of Management and Budget, Office of Information and Regulatory Affairs. Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, telephone: (202) 395–4638, fax: (202) 395–4718]. For security reasons, comments to OMB should be submitted by email to: oira_submission@omb.eop.gov. Comments submitted to OMB should include Docket Number RM12–14–000 and OMB Control Number 1902–0070.

V. Environmental Analysis

21. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.23 The Commission has categorically excluded certain actions from these requirements as not having a significant effect on the human environment.24 The actions set forth here fall within categorical exclusions in the Commission’s regulations for rules that are clarifying, corrective, or procedural, for information gathering, analysis, and dissemination, and for sales, exchange, and transportation of natural gas that requires no construction of facilities.25 Therefore, an environmental assessment is unnecessary and has not been prepared as part of this Final Rule.

VI. Regulatory Flexibility Act

22. The Regulatory Flexibility Act of 1980 (RFA)26 generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a Final Rule and that minimize any significant economic impact on a substantial number of small entities. The Small Business Administration’s (SBA) Office of Size Standards develops the numerical definition of a small business.27 The SBA has established a size standard for pipelines transporting natural gas, stating that a firm is small if its annual receipts are less than $25.5 million.28

23. The regulations set forth here impose requirements only on interstate pipelines, the majority of which are not small businesses. Most companies regulated by the Commission do not fall within the RFA’s definition of a small entity. Approximately 145 entities would be potential respondents subject to data collection FERC–545 reporting requirements. Nearly all of these entities are large entities. For the year 2011 (the most recent year for which information is available), only 15 companies not affiliated with larger companies had annual revenues of less than $25.5 million. Moreover, these requirements are designed to benefit all customers, including small businesses.

24. The Commission estimates that the one-time cost per small entity is $354.29 In the future, small entities should see a cost savings related to avoiding an annual ACA charge adjustment filing. The Commission does not consider the estimated $354 impact per entity to be significant. Accordingly, pursuant to § 605(b) of the RFA, the Commission certifies that this Final Rule should not have a significant economic impact on a substantial number of small entities.

VII. Document Availability

25. In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC’s Home Page ([http://www.ferc.gov](http://www.ferc.gov)) and in FERC’s Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

26. From FERC’s Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

27. User assistance is available for eLibrary and the FERC’s Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

VIII. Effective Date and Congressional Notification

28. These regulations are effective May 31, 2013. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a “major rule” as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects in 18 CFR Part 154

Natural gas, Pipelines, Reporting and recordkeeping requirements.

By the Commission.

Kimberly D. Bose,
Secretary.

In consideration of the foregoing, the Commission amends Parts 154, Chapter I, Title 18, Code of Federal Regulations, as follows:

PART 154–RATE SCHEDULES AND TARIFFS

1. The authority citation for part 154 continues to read as follows:


2. In § 154.402, revise paragraphs (a) and (b) to read as follows:

§ 154.402 ACA expenditures.

(a) Requirements. Upon approval by the Commission, a natural gas pipeline company may adjust its rates, annually, to recover from its customers annual charges assessed by the Commission under part 342 of this chapter pursuant to an annual charge adjustment clause (ACA clause). Prior to the start of each fiscal year, the Commission will post on...
its Web site the amount of annual charges to be flowed through per unit of energy sold or transported (ACA unit charge) for that fiscal year. A company’s ACA clause must be filed with the Commission and must incorporate by reference the ACA unit charge for the upcoming fiscal year as posted on the Commission’s Web site. A company must incorporate by reference the ACA unit charge posted on the Commission’s Web site in each of its rate schedules applicable to sales or transportation deliveries. The company must apply the ACA unit charge posted on the Commission’s Web site to the usage component of rate schedules with two-part rates. A company may recover annual charges through an ACA unit charge only if its rates do not otherwise reflect the costs of annual charges assessed by the Commission under §382.106(a) of this chapter. The applicable annual charge, required by §382.103 of this chapter, must be paid before the company applies the ACA unit charge. Upon payment to the Commission of its annual charges, the ACA unit charge for that fiscal year will be incorporated by reference into the company’s tariff, effective throughout that fiscal year.

(b) Application for rate treatment authorization. A company seeking authorization to use an ACA unit charge must file with the Commission a separate ACA tariff record containing:

(1) A statement that the company is collecting an ACA unit charge, as calculated by the Commission, applicable to all the pipeline’s sales and transportation rate schedules,

(2) A statement that the ACA unit charge, as revised annually and posted on the Commission’s Web site, is incorporated by reference into the company’s tariff,

(3) For companies with existing ACA clauses, a proposed effective date of the tariff change of October 1 of the fiscal year; for companies seeking to utilize an ACA clause after October 1 of the fiscal year, a proposed effective date 30 days after the filing of the tariff record, unless a shorter period is specifically requested in a waiver petition and approved,

(4) A statement that the pipeline will not recover any annual charges recorded in FERC Account 928 in a proceeding under subpart D of this part.

* * * * *

[FR Doc. 2013–07078 Filed 3–29–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73


Listing of Color Additives Exempt From Certification; Reactive Blue 246 and Reactive Blue 247 Copolymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of additional copolymers of 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (C.I. Reactive Blue 246) and copolymers of 1,4-bis[2-hydroxyethyl]amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester (C.I. Reactive Blue 247) as color additives in contact lenses. This action is in response to two color additive petitions (CAPs) filed by CooperVision, Inc.

DATES: This rule is effective May 2, 2013. See section VII for related information on the filing of objections. Submit either electronic or written objections and requests for a hearing by May 1, 2013.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2011–C–0344 (C.I. Reactive Blue 246) or FDA–2011–C–0463 (C.I. Reactive Blue 247), by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

• Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and the appropriate docket number (FDA–2011–C–0344 for C.I. Reactive Blue 246 or FDA–2011–C–0463 for C.I. Reactive Blue 247) for this rulemaking. All objections received will be posted without change to http://www.regulations.gov, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the SUPPLEMENTARY INFORMATION section.

Docket: For access to the docket to read background documents or objections received, go to http://www.regulations.gov and insert the docket numbers, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of June 28, 2011 (76 FR 37090), we announced that CooperVision, Inc., 6150 Stoneridge Mall Rd., suite 370, Pleasanton, CA 94588 (petitioner) had filed two color additive petitions (CAP 1C0291 and CAP 1C0292). The petitions proposed to amend the color additive regulations in 21 CFR part 73, subpart D, Medical Devices, to provide for the safe use of additional copolymers of 1,4-bis[2-hydroxyethyl]amino]-9,10-anthracenedione bis(2-methyl-2-propenoic)ester (C.I. Reactive Blue 247) and additional copolymers of 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (C.I. Reactive Blue 246) as color additives in contact lenses. The color additives are produced by copolymerizing the reactive dyes with various vinyl and/or acrylic monomers such that the dyes are bound covalently and cross-linked in the resulting polymer matrix.1

1 According to the International Union of Pure and Applied Chemistry (IUPAC), a vinyl polymer is prepared from a monomer containing the vinyl group —CH=CH2. Acrylic polymers are one subclass of vinyl polymers; however, not all acrylic polymers (e.g., methacrylic polymers) are vinyl polymers using the IUPAC definition (Ref. 1). The term “vinyl and/or acrylic monomers” includes monomers that form vinyl polymers, monomers that form acrylic polymers (e.g., acrylate, methacrylate, acrylamide, etc.), or any combination thereof.